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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,072	08/30/2001	David R. Lindsay	LIDR5001JP	8673

29889 7590 05/19/2003

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,072	LINDSAY, DAVID R.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2003 (paper no.4)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Receipt is acknowledged of the Information Disclosure Statement (IDS) filed 08/30/01 and the Response to Election filed 02/21/03.

Upon further review and consideration, the Election of Species filed 02/21/03, has been *withdrawn*.

Claims 1-20 are pending. Claims 1-20 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Palermo et al. (US Pat. No. 6,228,863 B1).

Palermo discloses a controlled release oral dosage pharmaceutical formulation comprising: an analgesically effective amount of an orally active opioid agonist together

with an opioid antagonist into an oral dosage form, wherein the amount of antagonist being sufficient to counteract the effects of the opioid agonist/antagonist combination to provide an aversive effect in a physically dependent human subject when the dosage is orally administered. A method of reducing the abuse potential of an oral dosage form of an opioid analgesic, which comprises combining an analgesically effective amount of an opioid agonist together with an opioid antagonist is also disclosed (see reference column 4, line 36 through column 6, line 35); and claims.

The opioid agonists disclosed are hydrocodone, hydromorphone, oxycodone, morphine sulfate, meperidine, codeine, methadone, or salts thereof, or mixtures thereof (col. 10, lines 8-15); and claims.

Opioid antagonists disclosed include, naltrexone, naloxone, nalmephene, cyclazocine and levallorphan (col. 8, lines 26-35).

Oral administration forms disclosed are tablets, capsules, liquids, powders or granules, microparticles, drops, lozenges, caplets, gelcaps and the like, for example (col. 6, lines 40-45); (col. 12, lines 45-50).

Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaiko et al. (US Pat. No. 6,277,384 B1).

Kaiko discloses a controlled release oral dosage formulation comprising a combination of an orally analgesically effective amount of an opioid agonist and an orally active opioid antagonist in an amount which does not cause a reduction in the

level of analgesia elicited from the dosage upon oral administration to a non-therapeutic level and which provides a mildly negative aversive experience in physically dependent human subjects. A method of preventing oral abuse of an oral opioid formulation by combining an opioid agonist together with an opioid antagonist is also disclosed (see reference column 4, line 46 through column 7, line 42); and claims.

The opioid agonists disclosed are, for example, hydrocodone, hydromorphone, oxymorphone, morphine, meperidine, salts and mixtures of any of the foregoing (col. 11, lines 34-57).

Opioid antagonists include, nalxone, naltrexone, nalmephene, cyclazocine (col. 10, lines 3-12).

Oral administration forms disclosed are tablets, capsules, liquids, powders or granules, microparticles, drops, lozenges, caplets, gelcaps and the like, for example (col. 7, lines 17-42).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
May 14, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600